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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,941	09/11/2003	Richard C. Potter	BASIC.034DV1C1	5072

20995 7590 07/14/2004

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EXAMINER
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HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/659,941

Applicant(s)

POTTER ET AL.

Examiner

Michael C. Henry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

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### **DETAILED ACTION**

Claims 1-8 are pending in application

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "68%" in claims 2, 12, 33, and 43 is a term which renders the claim indefinite. This term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what quantity (e.g. weight or volume) or units the 68% pertains to.

The term "concentrated" in claims 1, 11, 22 and 42 is a term which renders the claim indefinite. This term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. More specifically, it is unclear what concentration of the beta-glucan in the composition constitutes a concentrated beta-glucan composition.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-11,13-18-22, 24-32, 34-42, 44-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Misaki et al. (US 4,769,363).

Claim 1 is a product-by-process claim wherein the applicant claims “A physiologically acceptable concentrated beta-glucan composition comprising mixed (1,3)(1,4) linkages prepared in an alcohol free process in the absence of organic solvents. Misaki et al. disclose applicant’s physiologically acceptable concentrated beta-glucan composition comprising mixed (1,3)(1,4) linkages (see col. 3, lines 34 to col. 4, line 30; see also claim 1). A quotation from the MPEP (Manual of Patent Examining Procedure, 8 ed., August 2001) pertaining to Product-by-Process Claims is given below in order for further corroborate the reason for the aforementioned rejection. The quotation states that “PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE IMPLIED BY THE STEPS “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).” Claims 3-7 are which drawn to beta-glucan of claim 1 are also product-by-process claims which are rejected as being anticipated by Misaki et al. Claim 9 which is drawn to the composition of claim 1, wherein said beta- glucan is selected from those obtainable from oats, barley ....., is rejected by as being anticipated by Misaki et al. It should be noted that the source from which the beta-gluican is obtained does not add to the

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patentability of the composition. Moreover, the source from which the said beta-glucan is obtained does not limit the claimed composition. Claim 10 which is drawn to the composition of claim 1, wherein said glucan is formulated for oral administration is also rejected by Misaki et al., since applicant's claimed composition does not disclose any ingredient or substance that renders it different from Misaki et al.'s composition and suitable for oral administration. Claims 11,13-18, which are drawn to a dietary supplement for reducing low density lipoprotein and total serum cholesterol comprising concentrated beta-glucan are product by process claims which are anticipated by Misaki et al., since applicant's claimed dietary supplement composition does not recite any ingredient or substance that renders it different from Misaki et al.'s composition. It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Claim 20 which is drawn to the composition of claim 11, wherein said beta- glucan is selected from those obtainable from oats, barley ....., is rejected by as being anticipated by Misaki et al. It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Moreover, the source from which the said beta-glucan is obtained does not limit the claimed composition. Claim 21 which is drawn to the supplement of claim 11, wherein said beta glucan is formulated for oral administration, is rejected as being anticipated by Misaki et al., since applicant's claimed composition does not disclose any ingredient or substance that renders it different from Misaki et al.'s composition and suitable for oral administration.

Claims 22, 24-29 which are drawn to a composition comprising concentrated (1,3)(1,4) beta glucan in a cosmetic composition are product by process claims which are anticipated by Misaki et al., since applicant's claimed the said cosmetic composition does not recite any ingredient or substance that renders it different from Misaki et al.'s composition. It should be

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noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Claim 31 which is drawn to the composition of claim 22, wherein said beta-glucan is selected from those obtainable from oats, barley ....., is rejected by as being anticipated by Misaki et al. It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Moreover, the source from which the said beta-glucan is obtained does not limit the claimed composition.

Claims 32, 34-39 which are drawn to a composition comprising concentrated (1,3)(1,4) beta glucan in combination with a food product are product-by-process claims which are anticipated by Misaki et al., since Misaki et al.'s composition is also in combination with a food (batter flour) (see example 14, col. 11, lines 50-10). Claim 41 which is drawn to the composition of claim 32, wherein said beta- glucan is selected from those obtainable from oats, barley ....., is rejected by as being anticipated by Misaki et al. It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Moreover, the source from which the said beta-glucan is obtained does not limit the claimed composition.

Claims 42, 44-49 which are drawn to a pharmaceutical composition comprising concentrated (1,3)(1,4) beta glucan and a pharmaceutically acceptable carrier are product-by-process claims which are anticipated by Misaki et al., since Misaki et al.'s composition also contain water which his a pharmaceutically acceptable carrier. It should be noted that the source from which the beta-glucan is obtained does not add to the patentability of the composition. Claim 51 which is drawn to the composition of claim 42, wherein said beta- glucan is selected from those obtainable from oats, barley ....., is rejected by as being anticipated by Misaki et al. It should be noted that the source from which the beta-glucan is obtained does not add to the

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patentability of the composition. Moreover, the source from which the said beta-glucan is obtained does not limit the claimed composition. Claim 52 which is drawn to the supplement of claim 42, wherein said beta glucan is formulated for oral administration, is rejected as being anticipated by Misaki et al., since applicant's claimed composition does not disclose any ingredient or substance that renders it different from Misaki et al.'s composition and suitable for oral administration.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Misaki et al. (US 4,769,363).

In claim 1, applicant claims "A physiologically acceptable concentrated beta-glucan composition comprising mixed (1,3)(1,4) linkages prepared in an alcohol free process in the absence of organic solvents." In claim 2, applicant claims the composition of claim 1, wherein the concentration of the said beta glucan is greater than 68%. Dependent claims 12, 33 and 43 are drawn to compositions wherein the concentration of the said beta glucan is greater than 68%.

Misaki et al. disclose beta glucan compositions comprising mixed (1,3)(1,4) (see col. 3, lines 34 to col. 4, line 30; see claim 1; see also example 14, col. 11, lines 50-10).

The difference between applicant's claimed composition and the composition of Misaki et al. is that Misaki et al. is silent about the concentration in percent of beta-glucan. However,

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Misaki et al. disclose that the beta-glucan can be used in chemicals, food products, pharmaceuticals, etc (see col. 8, lines example 1, especially lines 44-45).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to prepare Misaki et al.'s beta glucan compositions comprising mixed (1,3)(1,4) of different percent concentration to be used as chemicals, food products or pharmaceuticals that are formulated, as disclosed by Misaki et al.

One having ordinary skill in the art would have been motivated, to have prepared Misaki et al.'s beta glucan compositions comprising mixed (1,3)(1,4) of different percent concentration to be used as chemicals, food products or pharmaceuticals that are formulated, as disclosed by Misaki et al.

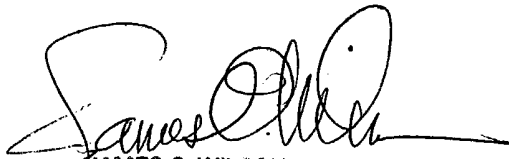
#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8:30 am to 5:00 pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-1235.

MCH

June 6, 2004.

  
JAMES O. WILSON  
SUPERVISORY PATENT EXAMINER  
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